DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-810/S-003
NDA 19-810/S-058

AstraZeneca LP
Attention: Nicholas J. Troise
Director, Regulatory Affairs
1800 Concord Pike
PO Box 8355
Wilmington, DE 19803-8355

Dear Mr. Troise:

Please refer to your supplemental new drug application, NDA 19-810/S-058, dated October 7, 1998, received October 7, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prilosec® (omeprazole) Delayed-Release Capsules.

We also refer to your supplemental new drug application, NDA 19-810/003, dated November 6, 1989, received November 7, 1989, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prilosec® (omeprazole) Delayed-Release Capsules.

We acknowledge receipt of your submissions dated December 22, 2003, received on December 23, 2003. Your submissions constituted a complete response to our October 3, 2003 action letter.

Supplemental new drug application, NDA 19-810/S-058, proposes revisions to the package insert under the ***Carcinogenicity, Mutagenicity, Impairment of Fertility/, Pregnancy/,*** **and** ***Nursing Mothers*** subsections of the **PRECAUTIONS** section.

Supplemental new drug application, NDA 19-810/003, proposes revisions to the package insert under the ***Carcinogenicity, Mutagenicity, Impairment of Fertility*** subsection of the **PRECAUTIONS** section, regarding a primary malignant tumor observed in a single rat.

We completed our review of these supplemental new drug applications. They are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on December 22, 2003.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Gastrointestinal and Coagulation Drug Products and two copies of both the promotional materials and the package inserts directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Monika Houstoun, Regulatory Project Manager, at (301) 827-9333.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D., M.S.
Director
Division of Gastrointestinal and
Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Joyce Korvick
2/23/04 04:23:23 PM
for Dr. Robert Justice